



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 30, 2016

**MEMORANDUM**

Subject: Efficacy Review for EPA File Symbol 4091-ER, Condor 2;  
DP Barcode: 434962  
E-Sub #: 12585

From: Marcus Rindal, Microbiologist  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

To: Eric Miederhoff PM 31/Karen Leavy  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: W.M. Barr & Company, Inc.  
6750 Lenox Center Court, Suite 200  
Memphis, TN 38115

**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl* dimethyl benzyl ammonium chloride (*50%C <sub>14</sub> , 40%C <sub>12</sub> , 10%C <sub>16</sub> ).....	0.200
Didecyl dimethyl ammonium chloride.....	0.115
Octyl decyl dimethyl ammonium chloride.....	0.075
Diocetyl dimethyl ammonium chloride.....	0.075
<u>Other Ingredients</u> .....	99.500
Total.....	100.000

## I BACKGROUND

The new/unregistered product, Condor 2 (EPA File Symbol 4091-ER), is a ready-to-use spray liquid for use as a one-step hard surface disinfectant with virucidal and fungicidal activity intended for use in indoor residential environments. The product is also a non-food contact surface sanitizer and residual (24 hour) sanitizer as well as a mildewstat for both hard and soft surfaces. Relevant efficacy studies were submitted to allow the product label to claim hard, nonporous surface disinfection (including supplemental bacterial, fungal, and viral claims), hard, nonporous surface sanitization, residual (24 hour) sanitization (using EPA protocol 01-1A), soft surface (fabric) sanitization, and mildewstatic properties for nonporous and fabric surfaces. The lots used in efficacy testing were formulated with the active ingredient at or below the lower certified limit. The chemical characterization reports for the lots used in each test are included in each efficacy report.

This data package contained a letter from the applicant's representative to EPA (dated July 1, 2016), EPA Form 8570-35 (Data Matrix), fourteen studies (MRID 499297-12 through 499297-25), Statements of No Data Confidentiality Claims for all studies, and the proposed label (version 101016).

## II USE DIRECTIONS

The proposed label (identified as Version 101016) provides the following use directions.

### {Sanitizing Directions}

Hold container 6"-8" from surface and spray until thoroughly wet.

To Sanitize Hard Non-porous surfaces: Let stand 10 seconds. Wipe clean with a [damp] cloth [or sponge] [or paper towel]. Pre-clean heavily soiled surfaces. [Kills [effective against] [99.9% of] {Insert non-food contact sanitization bacteria from Table B}.]

To Sanitize Hard Non-porous Surfaces FOR 24 HOURS: – Let stand 5 minutes. Allow to air dry. Pre-clean heavily soiled surfaces. [Kills [effective against] [99.9% of] {Insert residual sanitization bacteria from Table B} [for 24 hours].]

### {Disinfecting Directions}

Hold container 6"-8" from surface and spray until thoroughly wet.

TO DISINFECT [Bacteria][and viruses<sup>†</sup> on]Hard, non-porous surfaces: Let stand for 5 minutes. Wipe with a [damp] cloth [or sponge][or paper towel]. Preclean heavily soiled surfaces. [Kills [effective against] [99.9% of] {Insert disinfection bacteria and viruses from Table A.}]

### {Mildew Fungistatic Directions}

TO PREVENT MOLD [AND MILDEW] [growth]:

[Fabric Mildewstat] On [cotton and polyester] Fabrics:

[To inhibit mold and mildew growth]: Apply to fabric surface until wet [do not saturate]. Allow to air dry. Repeat [application] every 28 days to inhibit mold [and mildew] growth. [Effective against *Aspergillus niger* [(black mold)] [mildew] and *Penicillium variable*.] Pre-clean heavily soiled surfaces.

[Hard Surface Mildewstat] On hard surfaces:



[To inhibit mold and mildew growth]: Thoroughly wet surface. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against *Aspergillus niger* [(black mold)] [mildew]] Pre-clean heavily soiled surfaces.

### III COMMENTS ON THE SUBMITTED EFFICACY STUDIES

**1. MRID 499297-12, "AOAC Germicidal Spray Method," Test Organisms: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538) for Condor 2, Lot KK005-114, Lot KK005-115, and Lot KK005-116. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – March 10, 2016. Project Number A20212.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot KK005-114, Lot KK005-115, and Lot KK005-116) of the product, Condor 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120215.GS.2 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. A 10 µL aliquot of thawed frozen stock culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, without vortex mixing the *Pseudomonas aeruginosa* culture, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). One additional daily transfer was prepared for the *Pseudomonas* culture, and the *Salmonella* culture. The final test cultures were incubated for 48 hours at 35-37°C. During culture transfers, the *Pseudomonas* culture was not vortex mixed. On the day of use, the pellicle was carefully aspirated from the *Pseudomonas aeruginosa* culture by vacuum aspiration. Care was taken to avoid disrupting the pellicle and any visible pellicle on the bottom of the tube was not harvested. To avoid harvesting any visible pellicle at the bottom of the tube, the upper portion of the culture was transferred to a sterile tube. Any culture with disrupted pellicle was not used. Each test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The *Pseudomonas* culture was visually inspected to ensure no pellicle fragments were present. The *Salmonella* and *Staphylococcus* cultures were each diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 4.0 mL of sterile growth medium. The *Pseudomonas* culture was diluted using sterile growth medium by combining 2.00 mL of test organism suspension with 2.0 mL of sterile growth medium. The final test cultures were mixed thoroughly prior to use. An aliquot of FBS was added to each prepared culture to yield a 5% fetal bovine serum organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30-31 minutes at 35-37°C (36.3-36.6°C) and at 53.4% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface using 3 sprays. The carriers were allowed to remain wet for 1 minute at room temperature (20°C) and at 25% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Letheen Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence



or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**2. MRID 499297-13, "AOAC Germicidal Spray Method," Test Organism: *Escherichia coli* O157:H7 (ATCC 43888), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Carrie K. Bauer, Study completion date – May 4, 2016. Project Number A20588.**

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43888). Two lots (Lot KK005-114 and Lot KK005-116) of the product, Condor 2, were tested using Accuratus Laboratory Services Protocol No. WMB002032916.GS (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. A loop of stock slant culture was transferred to an initial 10 mL tube of growth medium. The tube was mixed and the initial culture was incubated for 24±2 hours at 35-37°C. Following incubation, a 10 µL aliquot of culture was transferred to a 20 x 150 mm Morton Closure tube containing 10 mL of culture medium (daily transfer #1). The final test cultures were incubated for 48 hours at 35-37°C. The test culture was vortex mixed (3-4 seconds) and allowed to stand ≥10 minutes prior to use. After this time, the upper portion of the culture was removed, leaving behind any clumps or debris and was pooled in a sterile vessel and mixed. The final test culture was mixed thoroughly prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of the prepared culture to yield a 5% fetal bovine serum organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.5°C) and at 52.9% relative humidity. Carriers were used within 2 hours of drying. Test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 3 sprays. The carriers were allowed to remain wet for 1 minute at room temperature (20°C) and at 27% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**3. MRID 499297-14, "Fungicidal Germicidal Spray Method," Test Organism: *Trichophyton mentagrophytes* (ATCC 9533), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Melissa Bruner. Study completion date – April 20, 2016. Project Number A20221.**

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot KK005-114 and Lot KK005-116) of the product, Phoenix 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120215.FGS.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. A culture of *Trichophyton mentagrophytes* was prepared by inoculating 30 agar plates using a stock culture and incubating at 25-30°C for 10 days. The mycelia were removed from sufficient plates using a sterile device. The mycelia were transferred to sterile glassware containing glass beads at a ratio of 25.0 mL of saline/Triton Solution (0.85% saline + 0.05% Triton X-100) per 5 plates harvested, and agitated. The culture was filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemocytometer. The viable cell count was  $4.7 \times 10^8$  CFU/mL. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture to yield a 5%



fetal bovine serum organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.6-36.7°C) and at 52.4% relative humidity. Carriers were used within 2 hours of drying. For each lot of prepared test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 3 sprays. The carriers were allowed to remain wet for 5 minute at room temperature (20°C) and at 17% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. All subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 66-76 hours at 25-30°C. Following incubation and storage, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**4. MRID 499297-15, "Fungicidal Germicidal Spray Method," Test Organism: *Aspergillus niger* (ATCC 6275), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Maggie Brusky. Study completion date – April 12, 2016. Project Number A20211.**

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (Lot KK005-114 and Lot KK005-116) of the product, Condor 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120215.FGS.2 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of Sabouraud Agar (Modified) with the stock culture and incubated for 8 days at 25-30°C. Following incubation, saline/Triton Solution (0.85% saline + 0.05% Triton X-100) and sterile glass beads were added to the flask. The flask was agitated to remove mycelia/conidia from the agar. The conidia suspension was aspirated from the flask and passed through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was  $1.9 \times 10^7$  CFU/mL. The test culture was thoroughly mixed prior to use. A 0.100 mL aliquot of FBS was added to 1.9 mL of prepared culture to yield a 5% Fetal Bovine Serum organic soil load. A 10 µL aliquot of the prepared culture was uniformly spread over the individual glass slide carriers (18 mm x 36 mm) per product batch, each in a Petri dish matted with two pieces of filter paper. Inoculum was uniformly spread over the test surface (approximately 1 square inch) of the slide in each Petri dish and covered immediately. This procedure was repeated until all slides were individually inoculated. The slides were allowed to dry for 30 minutes at 35-37°C (36.0°C) and at 51% relative humidity. Carriers were used within 2 hours of drying. For each lot of prepared test substance, test carriers were sprayed in a horizontal position with the test substance at a distance of 6-8 inches from the carrier surface for 3 sprays. The carriers were allowed to remain wet for 5 minute at room temperature (20.7°C) and at 26.5% relative humidity. Following the exposure period, excess liquid was drained off the carrier and the individual carriers were transferred using sterile forceps at identical staggered intervals to 20 mL of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize. All subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 44-52 hours at 25-30°C. Following incubation and storage, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

**5. MRID 4992967-16, "Virucidal Efficacy of a Disinfectant for Use on Inanimate**



**Environmental Surfaces,” Test Organism: Human Coronavirus (ATCC VR-740, Strain 229E), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Shanen Conway. Study completion date – April 22, 2016. Project Number A20197.**

This study was conducted against Human Coronavirus, ATCC VR-740, Strain 229E, for two lots of Condor 2, Lot numbers KK005-114 and KK005-116. These were tested using Accuratus Lab Services Protocol No. WMB002122115.COR (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum (FBS) as the organic soil load. Indicator cell cultures of WI-38 (Human lung) cells (ATCC CCL-75) demonstrated cytopathic effects (CPE) typical of Human Coronavirus on WI-38 cells. WI-38 indicator cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere at 5-7% CO<sub>2</sub>. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of spray released under use conditions for a contact time of one minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10<sup>-1</sup> dilution) were titrated by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The WI-38 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for 10 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

**6. MRID 499297-17, “Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces,” Test Organism: Herpes simplex virus type 1 (ATCC VR-733, Strain F(1)), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Mary J. Miller. Study completion date – April 14, 2016. Project Number A20201.**

This study was conducted against Herpes simplex virus type 1 (ATCC VR-733, Strain F(1)), for two lots of Condor 2, Lot numbers KK005-114 and KK005-116. These were tested using Accuratus Lab Services Protocol No. WMB002120715.HSV1.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus contained 5% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Herpes simplex virus on Vero cells. Cultures of Vero cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The confluency of the cells was appropriate for the test virus. The test



medium used for this assay was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of 3 sprays for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10<sup>-1</sup> dilution) were titrated by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Vero cell line, which exhibits cytopathic effect (CPE) in the presence of Herpes simplex virus type 1, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in duplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

**7. MRID 499297-18, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Herpes simplex virus type 2 (ATCC VR-734, Strain G), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Shanen Conway. Study completion date – May 2, 2016. Project Number A20198.**

This study was conducted against Herpes simplex virus type 2 (ATCC VR-734, Strain G), for two lots of Condor 2, Lot numbers KK005-114 and KK005-116. These were tested using Accuratus Lab Services Protocol No. WMB002120715.HSV2.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus contained 5% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Herpes simplex virus on Vero cells. Cultures of Vero cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of 3 sprays for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the



mixtures. The  $10^{-2}$  dilution for each lot of test substance was passed through a second individual Sephadex column utilizing the syringe plunger. The filtrates ( $10^{-1}$  dilution) were titrated by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Vero cell line, which exhibits cytopathic effect (CPE) in the presence of Herpes simplex virus type 2, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in quadruplicate with 100  $\mu$ L of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

**8. MRID 499297-19, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: 2009-H1N1 Influenza A virus (Novel H1N1) (Strain A/Mexico/4108/2009 CDC #2009712192), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Shanen Conway. Study completion date – April 22, 2016. Project Number A20199.**

This study was conducted against 2009-H1N1 Influenza A virus (Novel H1N1) (Strain A/Mexico/4108/2009 CDC #2009712192), for two lots of Condor 2, Lot numbers KK005-114 and KK005-116. These were tested using Accuratus Lab Services Protocol No. WMB002120715.FLUA.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Influenza virus (Novel H1N1) on MDCK (canine kidney) cells. Cultures of MDCK cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10  $\mu$ g/mL gentamicin, 100 units/mL penicillin and 2.5  $\mu$ g/mL amphotericin B, 2  $\mu$ g/mL TPCK-Trypsin, 25 mM Hepes, and 0.2% BSA fraction V. Dried virus films were prepared by spreading 200  $\mu$ L of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 21.0°C in a relative humidity of 40% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of 3 sprays for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates ( $10^{-1}$  dilution) were titrated by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MDCK cell line, which exhibits cytopathic effect (CPE) in the presence of Influenza virus, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in quadruplicate with 100  $\mu$ L of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.



**9. MRID 499297-20, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Respiratory syncytial virus (ATCC VR-26, Strain Long), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Mary J. Miller. Study completion date – April 14, 2016. Project Number A20223.**

This study was conducted against Respiratory syncytial virus (ATCC VR-26, Strain Long), for two lots of Condor 2, Lot numbers KK005-114 and KK005-116. These were tested using Accuratus Lab Services Protocol No. WMB002120715.RSV.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum (FBS) as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Respiratory syncytial virus (RSV) on Hep-2 (human larynx carcinoma) cells. Cultures of Hep-2 cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The confluency of the cells was appropriate for the test virus. The test medium used for this assay was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat inactivated fetal bovine serum. The medium was also supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 1.0 mM L-glutamine, and 2.5 µg/mL amphotericin B. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 50% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of 3 sprays for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10<sup>-1</sup> dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The Hep-2 cell line, which exhibits cytopathic effect (CPE) in the presence of Respiratory syncytial virus (RSV), was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in duplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for 9 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

**10. MRID 499297-21, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Rotavirus (ATCC VR-2018, Strain WA), for Condor 2, Lot KK005-114 and Lot KK005-116. Study conducted at Accuratus Lab Services by Mary J. Miller. Study completion date – April 11, 2016. Project Number A20210.**

This study was conducted against Rotavirus (ATCC VR-2018, Strain WA), for two lots of Condor 2, Lot numbers KK005-114 and KK005-116. These were tested using Accuratus Lab Services Protocol No. WMB002120715.ROT.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. On the day of use, an aliquot of stock virus was thawed and maintained at a refrigerated temperature until used in the assay. The stock virus was adjusted to contain 5% fetal bovine serum (FBS) as the organic soil load. The stock virus tested



demonstrated cytopathic effects (CPE) typical of Rotavirus on MA-104 cells. Cultures of MA-104 (Rhesus monkey kidney) cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub>. The confluency of the cells was appropriate for the test virus. The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 0.5 µg/mL trypsin and 2.0 mM L-glutamine. Dried virus films were prepared by spreading 200 µL of test virus inoculum uniformly over the bottoms of 3 separate 100 x 15 mm sterile glass petri dishes. These were dried at 20.0°C in a relative humidity of 40% for 20 minutes. To reduce the cytotoxic level of the virus-test substance mixture prior to assay of virus, and/or to reduce the virucidal level of the test substance, virus was separated from the test substance by filtration through Sephadex LH-20 gel. On the day of testing, Sephadex columns were prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. For each lot of test substance, one dried virus film was exposed by being completely covered by the amount of 3 sprays for a contact time of 1 minute. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to re-suspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates (10<sup>-1</sup> dilution) were titered by 10-fold serial dilution and each dilution was then assayed for infectivity and/or cytotoxicity. The MA-104 cell line, which exhibits cytopathic effect (CPE) in the presence of Rotavirus, was used as the indicator cell line in the infectivity assays. The cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions prepared from test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO<sub>2</sub> in sterile disposable cell culture labware. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus control, cytotoxicity, neutralization and cell viability.

**11. MRID 499297-22, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)," Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538), for Condor 2, Lot KK005-114, Lot KK005-115, and KK005-116. Study conducted at Accuratus Lab Services by Jamie Herzan. Study completion date – March 8, 2016. Project Number A20177.**

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot KK005-114, Lot KK005-115, and Lot KK005-116) of the product, Condor 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.NFS.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. From a stock slant no more than 5 transfers from original stock and ≤1 month old, an initial tube (10 mL) of culture broth was inoculated. This culture was termed the "initial broth suspension." From this initial broth suspension, a minimum of three daily transfers using 1 loopful (10 µL) of culture into 10 mL of culture media was performed on consecutive days prior to use as an inoculum. Each daily transfer was incubated for 24±2 hours using the appropriate growth medium. A 48-54 hour culture was vortex-mixed and allowed to settle for ≥15 minutes. The upper 2/3rds of the culture was removed and transferred to a sterile vessel for use in testing. The *Enterobacter aerogenes* culture was diluted using sterile growth medium by combining 1.00 mL of test organism suspension with 4.00 mL of sterile growth medium. The *Staphylococcus aureus* culture was diluted using sterile growth medium by combining 3.00 mL of test organism suspension with 3.00 mL of sterile growth medium. The cultures were thoroughly mixed prior to use. A 0.10 mL aliquot of FBS was added to 1.90 mL of each prepared culture to yield a 5% fetal bovine serum organic soil load. Sterile carriers were inoculated with 0.02 mL (20.0 µL) of culture using a calibrated pipettor spreading the inoculum to within approximately 3 mm of



the edges of the carrier. The inoculated carriers were dried for 20 minutes at 35-37°C (36.1°C) and 40% relative humidity with the Petri dish lids slightly ajar. Following the completion of drying, each of the five test carriers were sprayed with test substance using staggered intervals. Carriers were sprayed at a distance of 6-8 inches until thoroughly wet (3 spray used) and were allowed to expose at room temperature (20°C) and 23% relative humidity for 10 seconds. Following exposure, each carrier was transferred to 20 mL of neutralizer using identical staggered intervals. Following the neutralization of the test carriers, the excess liquid in each Petri dish was transferred to the neutralizer jar containing the matching carrier. The jars were vortex-mixed for 10-15 seconds to suspend the surviving organisms. Within 30 minutes of neutralization, duplicate 1.00 mL and 0.100 mL aliquots of the neutralized solution ( $10^0$ ) were plated onto the recovery agar plate medium. The *S. aureus* plates were incubated at 35-37°C for 48±4 hours. The *E. aerogenes* plates were incubated for 48±4 hours at 25-32°C. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually enumerated. Controls included those for carrier population, media sterility, culture purity, neutralization confirmation, and inoculum count.

**12. MRID 499297-23, "Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces (with exposure and wear activity)," Test Organisms: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538), for Condor 2, Lot KK005-114, Lot KK005-115, and KK005-116. Study conducted at Accuratus Lab Services by Matthew Sathe. Study completion date – May 3, 2016. Project Number A20242.**

This study was conducted against *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot KK005-114, Lot KK005-115, and Lot KK005-116) of the product, Condor 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.RES.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. From a stock slant an initial tube (10 mL) of culture broth was inoculated. This culture was termed the "initial broth suspension." From this initial broth suspension, a minimum of three daily transfers using 1 loopful (10 µL) of culture into 10 mL of culture media were performed on consecutive days prior to use in testing procedure.

**For the initial inoculation culture**, a 48-54 hour culture, per test organism, was vortex mixed and was allowed to stand for 15±1 minutes. Using the upper 2/3rds of inoculum, the culture was serially diluted by adding 0.100 mL of culture to 9.9 mL of sterile deionized water. This serial dilution was repeated a second time yielding a total of two 1:100 dilutions. The concentration of each final (diluted) initial inoculation culture was determined by serial dilution and standard plating technique (initial suspension control). A 0.20 mL aliquot of FBS was added to 3.80 mL of diluted culture to yield a 5% fetal bovine serum organic soil load. The final culture was mixed and allowed to stand at least 15±1 minutes prior to use.

**For the reinoculation culture**, an 18-24 hour culture, per test organism, was vortex mixed and was allowed to stand for 15±1 minutes. Using the upper 2/3rds of inoculum, the culture was serially diluted by adding 0.100 mL of culture to 9.9 mL of sterile deionized water. This serial dilution was repeated a second time yielding a total of two 1:100 dilutions. Finally, the culture was diluted 1:2 by combining 5.0 mL of culture with 5.0 mL of sterile deionized water. The concentration of each final (diluted) 18-24 hour reinoculation culture was determined by serial dilution and standard plating technique (initial suspension control). A 0.30 mL aliquot of FBS was added to 5.70 mL of diluted culture to yield a 5% fetal bovine serum organic soil load. The final culture was mixed and allowed to stand at least 15±1 minutes prior to use. No culture with organic soil load was allowed to stand >8 hours prior to use.



**For the sanitizer test culture**, an 18-24 hour culture, per test organism, was vortex mixed and was allowed to stand for at least 15±1 minutes. The upper 2/3rds of inoculum was removed by aspiration for inoculation. To target 5.88-6.38 log<sub>10</sub>/carrier, the *Enterobacter aerogenes* culture was diluted 1:7 in tryptic soy broth and *Staphylococcus aureus* was not diluted. The concentration of each sanitizer test culture was determined by serial dilution and standard plating technique (initial suspension control). A 0.30 mL aliquot of FBS was added to 5.70 mL of prepared culture to yield a 5% fetal bovine serum organic soil load. The final culture was mixed and allowed to stand at least 15±1 minutes prior to use.

#### **Initial Inoculation Procedure**

Using the prepared initial inoculation culture, a 10.0 µL aliquot was applied to each test and numbers control carrier, spreading the inoculum with a bent needle (hook) to within approximately 1/8th inch from the edge of the carrier. The carriers were dried, with the Petri dish lids slightly ajar, at 35-37°C for 30 minutes, until visibly dry.

#### **Application of the Test and Control Substance**

To avoid filter paper buckling in the Petri dish, 4 square glass carriers were placed inside a glass Petri dish with 1 piece of Whatman filter paper, weighed down by sterile stainless steel carriers. The test substance was then applied to all 4 replicate carriers (in the same dish) by spraying 3 pumps onto the center of the petri dish at a 45° angle, with the nozzle of the sprayer 6"-8" above the carrier surface. The treated carriers were dried uncovered in an environmental chamber set at 20°C and 48% relative humidity (RH) targeting 20-23°C and 45-48% RH (20.0°C and 48% RH) for 17.5 hours until completely dry. Similarly, a sterile solution of 0.01% Triton-X-100 solution was applied to each inoculated, dried numbers control carrier using 3 pumps from a trigger sprayer held at a 6-8" distance. The control carriers were allowed to dry as described for the test carriers. Inoculated, treated and dried test and numbers control carriers underwent a wear and reinoculation regimen, which took place over ≥24 hours at ambient temperature and humidity conditions. Two carriers underwent the wearing procedure simultaneously, per abrasion boat. The abrasion boat apparatus was assembled with sufficient weights, a foam liner and a sterile cotton liner such that the actual weight of the assembled boat was equal to 1084±0.2 g. Glass 4"x4" spacers were used on the wear tester and changed out every wear for disinfected spacers. The spacers were dry wiped before each wear. The actual weight of the abrasion boat assembly was recorded each time it was assembled and used. Only one weigh boat was used at a time during wears. In between wear cycle sets, the abrasion boat apparatus was disassembled and the cotton liner was replaced with a fresh, sterile cotton liner. The foam liner was replaced as needed and between organisms. Additionally, the abrasion tester was decontaminated with absolute ethanol in between cycle sets allowing the alcohol to completely evaporate before re-use. Alternating dry and wet cycles were performed. Wet wear cycles were performed by wetting the cotton liner attached to the weight boat assembly with sterile deionized water, using a Preval sprayer (or equivalent). This was achieved by misting the liner from a distance of approximately 75±1 cm for less than or equal to one second. Immediately after wetting, the moistened abrasion boat was attached to the abrasion tester and was used.

#### **Reinoculation procedure**

After an entire wear cycle was complete (i.e. all test and control carriers underwent the wear procedure), each test and numbers control carrier was reinoculated. Reinoculation occurred ≥15 minutes after the wear procedure was performed for the given carrier. Using the prepared reinoculation culture inoculum, a 10.0 µL aliquot was applied to each carrier spreading to within approximately 1/8th inch from the edge of the carrier. The reinoculated carriers were uncovered and dried for ≥30 minutes in an environmental chamber set at 20°C and 48% RH, prior to initiating



the next wear cycle or the sanitizer test. Carriers were not reinoculated following the final wear cycle. A total of 12 wear cycles alternated by 5 reinoculations were performed. Actual ambient conditions were periodically measured during the wear and reinoculation procedure. During the wear procedure, the temperature was 18-20°C and the relative humidity range was 8-12%.

### **Sanitizer Test**

At least 15 minutes after the final wear cycle (and at least 24 hours after test substance application), the sanitizer test was initiated. Using the prepared sanitizer test culture, each test and numbers control carrier was inoculated with 10.0 µl of culture spreading the inoculum with a bent needle (hook) to within approximately 1/8th inch from the edge of the carrier. The culture was applied at staggered intervals using a calibrated timer. The carriers were allowed to expose at ambient conditions (21°C and 47% relative humidity) for 4.5 minutes. Exposure began for each carrier as it was inoculated. Once the exposure period was achieved, each test and numbers control carrier was subcultured (at identical staggered intervals) into 30 mL of neutralizer broth using sterile forceps (representing a 10<sup>0</sup> dilution). This was continued until all test and numbers control carriers were subcultured. Following subculturing, each subculture was sonicated for 20 seconds. Each sonicated subculture was mixed on an orbital shaker for 3 minutes set to approximately 250 RPM. Within 30 minutes of neutralization, ten-fold serial dilutions were prepared using a sterile diluent. For the test subcultures, 1.00 mL aliquots of 10<sup>0</sup> through 10<sup>-3</sup> were pour-plated in duplicate onto the recovery agar plate medium. For the numbers control carriers, 1.00 mL aliquots of 10<sup>-1</sup> through 10<sup>-4</sup> were pour-plated in duplicate onto the recovery agar plate medium.

### **Incubation and Observation**

Plates and controls were incubated for 48-54 hours, at 35-37°C for *S. aureus* and 28-32°C for *E. aerogenes*. Subcultures from 2/18/16 were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually examined for growth. If possible, plates containing between 30 and 300 CFU were counted. On 4/22/16, representative test and positive control subcultures showing growth were visually examined, Gram stained, and biochemically assayed to confirm or rule out the presence of the test organism.

**13. MRID 499297-24, "EPA Hard Surface Mildew-Fungistatic Test," Test Organism: *Aspergillus niger* (ATCC 6275), for Condor 2, Lot KK005-114, and Lot KK005-116. Study conducted at Accuratus Lab Services by Jamie Herzan. Study completion date – March 8, 2016. Project Number A20245.**

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (Lot KK005-114 and Lot KK005-116) of the product, Condor 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.MSTAT.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor.

A flask of neopeptone agar was inoculated with a conidial suspension of the test organism and incubated 8 days at 25-30°C. After addition of a sterile saline solution/Triton Solution and glass beads, the flask was agitated to remove the mycelia/conidia. Hyphal fragments were removed and the conidial concentration was estimated by counting in a hemacytometer. The conidial count was 1.38×10<sup>7</sup> CFU/mL. A 2.00 mL aliquot of this suspension was added to 40.0 mL sterile Czapek's solution. A 2.00 mL aliquot of FBS was added to 38.0 mL of prepared Czapek/organism suspension to yield a 5% fetal bovine serum soil load. Ten (10) glazed ceramic tile carriers per product batch were sprayed with the product at a distance of 6 – 8 inches using 3 sprays (3 sprays used). The treated carriers were placed in a vertical or near vertical position to



permit excess liquid to drain. The carriers were dried in Petri dishes at 35-37°C for 20 minutes with the lids ajar. Untreated carriers were placed in sterile Petri dishes and dried for 20 minutes at 35-37°C with the lids ajar alongside the test carriers. The test organism suspension was sprayed onto the surface of the treated carrier with an atomizer. Approximately 3 sprays were used, and the atomizer was periodically mixed during inoculation. The carriers were dried at 35-37°C for 20 minutes and then transferred to individual water agar plates. Plates were incubated 7 days at 25-30°C in a minimum 95% relative humidity, and then visually examined for growth. Controls included those for purity, sterility, and an untreated control carrier.

**14. MRID 499297-25, "Fabric Mildew Fungistatic Test," Test Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333), for Condor 2, Lot KK005-114, and Lot KK005-116. Study conducted at Accuratus Lab Services by Matthew Sathe. Study completion date – May 4, 2016. Project Number A20195.**

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Two lots (Lot KK005-114 and Lot KK005-116) of the product, Condor 2, were tested using Accuratus Laboratory Services Protocol No. WMB002120715.FMSTAT.1 (copy provided). The product was received as a ready-to-use spray liquid from the sponsor. The *Aspergillus niger* conidial suspension was prepared by inoculating a flask of neopeptone agar was inoculated with a conidial suspension of the test organism and incubated 8 days at 25-30°C. After addition of a sterile saline solution/Triton Solution and glass beads, the flask was agitated to remove the mycelia/conidia. Hyphal fragments were removed and the conidial concentration was estimated by counting in a hemacytometer. The viable cell count was  $1.38 \times 10^7$  CFU/mL. The conidial suspension was standardized to contain an approximate target of  $5 \times 10^6$  conidia per mL by combining 20.0 mL of culture with 40.0 mL 0.85% saline. The *Penicillium variable* conidial suspension was prepared by inoculating 30 Sabouraud Dextrose agar plates (also known as Emmons agar) and incubating at 25-30°C for 10 days. Following incubation, 3.0 mL of sterile saline/Triton Solution (0.85% Saline + 0.05 % Triton X-100) was added to each plate harvested. The growth was harvested from the agar surface using a cell scraper. The harvested growth was transferred to a sterile vessel containing sterile beads and was hand swirled thoroughly. The culture was then filtered through sterile gauze to remove hyphal fragments. The conidial concentration was estimated by counting in a hemacytometer. The viable cell count was  $3.9 \times 10^8$  CFU/mL. The conidial suspension was standardized to contain an approximate target of  $5 \times 10^6$  conidia per mL by combining 1.00 mL of culture with 79.0 mL 0.85% saline. For each lot of test substance, each side of 10 test carriers were sprayed with the test substance at a distance of 6-8 inches using 3 sprays. The treated carriers were placed in a vertical or near vertical position to permit excess liquid to drain. The carriers were dried at room temperature (22.4-23.1°C) for 20 minutes until dry. Equal volumes (9.5 mL) of each well-mixed conidial suspension were combined within a DeVilbiss atomizer. A 1.00 mL aliquot of FBS was added to the 19.0 mL of combined organism suspension to yield a 5% fetal bovine serum soil load. Both sides of each fabric test carrier strip were lightly sprayed 3 times on each side using 6 total sprays. The culture was mixed periodically within the atomizer during spraying. The fabric test and control samples were suspended in individual 250 mL French Square bottles containing approximately 10 mL sterile deionized water and incubated at 25-30°C. The caps were tightened and then backed off approximately 1/8 turn to allow for ventilation. It was ensured that no fabric was touching the water at the time of incubation. The control plates and organic soil load sterility control were incubated for 2 days at 25-30°C. The subcultures were refrigerated for 2 days at 2-8°C prior to examination. Observations were made and recorded every 7 days for four weeks. The presence or absence of observable mold on the test carriers was the criterion for determining the effectiveness of the test product. Where no growth was visually evident at each weekly observation, a magnified



examination was conducted to confirm the absence or establish the presence of sub-visual growth. Controls included those for purity, sterility, and an untreated control carrier.

#### IV RESULTS

##### AOAC Germicidal Spray Products Test Results for Bacteria and Fungi

MRID	Organism	Organism Designation	Lot No.	No. of Carriers Exhibiting Growth/ Total No. Tested	Carrier Population (Log <sub>10</sub> CFU/Carrier)
1-Minute Exposure Time ----- 5% FBS Soil Load					
499297-12	<i>Pseudomonas aeruginosa</i>	ATCC 15442	KK005-114	0/60	5.14
			KK005-115	0/60	
			KK005-116	0/60	
	<i>Salmonella enterica</i>	ATCC 10708	KK005-114	0/60	4.47
			KK005-115	0/60	
			KK005-116	0/60	
	<i>Staphylococcus aureus</i>	ATCC 6538	KK005-114	0/60	5.47
			KK005-115	0/60	
			KK005-116	0/60	
499297-13	<i>Escherichia coli</i> O157:H7	ATCC 43888	KK005-114 KK005-116	0/10 0/10	6.31
5-Minute Exposure Time ----- 5% FBS Soil Load					
499297-14	<i>Trichophyton mentagrophytes</i>	ATCC 9533	KK005-114 KK005-116	0/10 0/10	4.92
499297-15	<i>Aspergillus niger</i>	ATCC 6275	KK005-114 KK005-116	0/10 0/10	5.01



# Virucidal Spray Test Method Results

MRID	Organism	Dilutions	Lot No. KK005-114	Lot No. KK005-116	Dried Virus Count
1-Minute Contact Time ----- 5% Organic Soil Added					
499297-16	Human Coronavirus (ATCC VR-740, Strain 229E)	10 <sup>-1</sup> to 10 <sup>-7</sup> Dilutions	Complete inactivation	Complete inactivation	10 <sup>5.50</sup> TCID <sub>50</sub> / 100 µL
		TCID <sub>50</sub> /100 µL	≤10 <sup>2.50</sup>	≤10 <sup>2.50</sup>	
499297-17	Herpes simplex virus type 1 (ATCC VR-733, Strain F(1))	10 <sup>-1</sup> to 10 <sup>-7</sup> Dilutions	Complete inactivation	Complete inactivation	10 <sup>5.50</sup> TCID <sub>50</sub> / 100 µL
		TCID <sub>50</sub> /100 µL	≤10 <sup>2.50</sup>	≤10 <sup>2.50</sup>	
499297-18	Herpes simplex virus type 2 (ATCC VR-734, Strain G)	10 <sup>-1</sup> to 10 <sup>-8</sup> Dilutions	Complete inactivation	Complete inactivation	10 <sup>4.75</sup> TCID <sub>50</sub> / 100 µL
		TCID <sub>50</sub> /100 µL	≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>	
499297-19	2009-H1N1 Influenza A virus (Novel H1N1) (Strain A/Mexico/4108/2009 CDC #2009712192)	10 <sup>-1</sup> to 10 <sup>-8</sup> Dilutions	Complete inactivation	Complete inactivation	10 <sup>6.00</sup> TCID <sub>50</sub> / 100 µL
		TCID <sub>50</sub> /100 µL	≤10 <sup>2.50</sup>	≤10 <sup>2.50</sup>	
499297-20	Respiratory syncytial virus (ATCC VR-26, Strain Long)	10 <sup>-1</sup> to 10 <sup>-7</sup> Dilutions	Complete inactivation	Complete inactivation	10 <sup>4.75</sup> TCID <sub>50</sub> / 100 µL
		TCID <sub>50</sub> /100 µL	≤10 <sup>0.50</sup>	≤10 <sup>1.50</sup>	
5-Minute Contact Time ----- 5% FBS Soil Load					
499297-21	Rotavirus (ATCC VR- 2018, Strain WA)	10 <sup>-1</sup> to 10 <sup>-8</sup> Dilutions	Complete inactivation	Complete inactivation	10 <sup>5.50</sup> TCID <sub>50</sub> / 100 µL
		TCID <sub>50</sub> /100 µL	≤10 <sup>1.50</sup>	≤10 <sup>1.50</sup>	



MRID 499297-22 Non-Food Contact Surface Sanitizer Testing Results

Test Organism: <i>Enterobacter aerogenes</i> (ATCC 13048)				10 sec. Contact Time		
Test Substance	Carrier #	CFU/Carrier	Log <sub>10</sub>	Avg. Log <sub>10</sub>	Geometric Mean	Reduction
Lot No. KK005-114	1	<2×10 <sup>1</sup>	<1.30	<1.30	<2.00×10 <sup>1</sup>	>99.9%
	2	<2×10 <sup>1</sup>	<1.30			
	3	<2×10 <sup>1</sup>	<1.30			
	4	<2×10 <sup>1</sup>	<1.30			
	5	<2×10 <sup>1</sup>	<1.30			
Lot No. KK005-115	1	<2×10 <sup>1</sup>	<1.30	<1.30	<2.00×10 <sup>1</sup>	>99.9%
	2	<2×10 <sup>1</sup>	<1.30			
	3	<2×10 <sup>1</sup>	<1.30			
	4	<2×10 <sup>1</sup>	<1.30			
	5	<2×10 <sup>1</sup>	<1.30			
Lot No. KK005-116	1	<2×10 <sup>1</sup>	<1.30	<1.30	<2.00×10 <sup>1</sup>	>99.9%
	2	<2×10 <sup>1</sup>	<1.30			
	3	<2×10 <sup>1</sup>	<1.30			
	4	<2×10 <sup>1</sup>	<1.30			
	5	<2×10 <sup>1</sup>	<1.30			
Test Organism: <i>Staphylococcus aureus</i> (ATCC 6538)				10 sec. Contact Time		
Test Substance	Carrier #	CFU/Carrier	Log <sub>10</sub>	Avg. Log <sub>10</sub>	Geometric Mean	Reduction
Lot No. KK005-114	1	<2×10 <sup>2</sup>	<2.30	<2.30	<2.00×10 <sup>2</sup>	>99.9%
	2	<2×10 <sup>2</sup>	<2.30			
	3	<2×10 <sup>2</sup>	<2.30			
	4	<2×10 <sup>2</sup>	<2.30			
	5	<2×10 <sup>2</sup>	<2.30			
Lot No. KK005-115	1	<2×10 <sup>2</sup>	<2.30	<2.30	<2.00×10 <sup>2</sup>	>99.9%
	2	<2×10 <sup>2</sup>	<2.30			
	3	<2×10 <sup>2</sup>	<2.30			
	4	<2×10 <sup>2</sup>	<2.30			
	5	<2×10 <sup>2</sup>	<2.30			
Lot No. KK005-116	1	<2×10 <sup>2</sup>	<2.30	<2.30	<2.00×10 <sup>2</sup>	>99.9%
	2	<2×10 <sup>2</sup>	<2.30			
	3	<2×10 <sup>2</sup>	<2.30			
	4	<2×10 <sup>2</sup>	<2.30			
	5	<2×10 <sup>2</sup>	<2.30			



## MRID 499297-23      Residual Self-Sanitizing Activity of Dried Chemical Residues – Results

Test Organism: <i>Enterobacter aerogenes</i> (ATCC 13048)						
Test Substance	Carrier #	CFU/Carrier	Log <sub>10</sub>	Avg. Log <sub>10</sub>	Geometric Mean	Reduction
Lot No. KK005-114	1	<3×10 <sup>1</sup>	<1.48	<1.48	<3.02×10 <sup>1</sup>	>99.9%
	2	<3×10 <sup>1</sup>	<1.48			
	3	<3×10 <sup>1</sup>	<1.48			
	4	<3×10 <sup>1</sup>	<1.48			
Lot No. KK005-115	1	4.9×10 <sup>3</sup>	3.69	<2.78	<6.03×10 <sup>2</sup>	>99.9%
	2	6.3×10 <sup>2</sup>	2.80			
	3	<3×10 <sup>1</sup>	<1.48			
	4	1.4×10 <sup>3</sup>	3.15			
Lot No. KK005-116	1	1.1×10 <sup>4</sup>	4.04	3.38	2.40×10 <sup>3</sup>	>99.9%
	2	1.9×10 <sup>4</sup>	4.28			
	3	2×10 <sup>2</sup>	2.30			
	4	7.8×10 <sup>2</sup>	2.89			

Test Organism: <i>Staphylococcus aureus</i> (ATCC 6538)						
Test Substance	Carrier #	CFU/Carrier	Log <sub>10</sub>	Avg. Log <sub>10</sub>	Geometric Mean	Reduction
Lot No. KK005-114	1	<3×10 <sup>1</sup>	<1.48	<1.48	<3.02×10 <sup>1</sup>	>99.9%
	2	<3×10 <sup>1</sup>	<1.48			
	3	<3×10 <sup>1</sup>	<1.48			
	4	<3×10 <sup>1</sup>	<1.48			
Lot No. KK005-115	1	<3×10 <sup>1</sup>	<1.48	<1.48	<3.02×10 <sup>1</sup>	99.9%
	2	<3×10 <sup>1</sup>	<1.48			
	3	<3×10 <sup>1</sup>	<1.48			
	4	<3×10 <sup>1</sup>	<1.48			
Lot No. KK005-116	1	<3×10 <sup>1</sup>	<1.48	<1.48	<3.02×10 <sup>1</sup>	>99.9%
	2	<3×10 <sup>1</sup>	<1.48			
	3	<3×10 <sup>1</sup>	<1.48			
	4	<3×10 <sup>1</sup>	<1.48			



# Hard Surface Fungistat Spray Results

MRID	Organism	Carrier No.	Percentage Growth Coverage at Day 7				
			Untreated Control	Lot KK005-114		Lot KK005-116	
				Visual	Magnified	Visual	Magnified
499297-24	<i>Aspergillus niger</i> (ATCC 6275)	1	65%	0%	No Growth	0%	No Growth
		2	85%	0%	No Growth	0%	No Growth
		3	90%	0%	No Growth	0%	No Growth
		4	95%	0%	No Growth	0%	No Growth
		5	95%	0%	No Growth	0%	No Growth
		6	90%	0%	No Growth	0%	No Growth
		7	85%	0%	No Growth	0%	No Growth
		8	85%	0%	No Growth	0%	No Growth
		9	75%	0%	No Growth	0%	No Growth
		10	80%	0%	No Growth	0%	No Growth

## MRID 499297-25 Test Results for Condor 2, Lot KK005-114

Test Organisms: <i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)								
Carrier #	Evaluation of Test Carriers							
	Day 7		Day 14		Day 21		Day 28	
	Visual	Magnified	Visual	Magnified	Visual	Magnified	Visual	Magnified
1	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
2	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
3	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
4	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
5	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
6	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
7	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
8	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
9	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
10	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth

## MRID 499297-25 Test Results for Condor 2, Lot KK005-116

Test Organisms: <i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)								
Carrier #	Evaluation of Test Carriers							
	Day 7		Day 14		Day 21		Day 28	
	Visual	Magnified	Visual	Magnified	Visual	Magnified	Visual	Magnified
1	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
2	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
3	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
4	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
5	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
6	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
7	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
8	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
9	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
10	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth



## V CONCLUSIONS

1. The submitted efficacy data **support** the product as a ready-to-use disinfectant against the following organisms in the presence of 5% organic soil on hard, non-porous surfaces, for a 1-minute contact time at room temperature (20-21°C):

<i>Pseudomonas aeruginosa</i>	ATCC 15442	499297-12
<i>Salmonella enterica</i>	ATCC 10708	499297-12
<i>Staphylococcus aureus</i>	ATCC 6538	499297-12
<i>Escherichia coli</i> O157:H7	ATCC 43888	499297-13

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Control counts were acceptable.

2. The submitted efficacy data **support** the ready-to-use product as a disinfectant with fungicidal activity against the following fungi on hard, non-porous surfaces, with 5% organic soil load for a 5-minute contact time at room temperature (20-21°C):

<i>Trichophyton mentagrophytes</i>	ATCC 9533	499297-14
<i>Aspergillus niger</i>	ATCC 6275	499297-15

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Control counts were acceptable.

3. The submitted efficacy data **support** the ready-to-use product as a disinfectant with virucidal activity against the following viruses on hard non-porous surfaces with 5% organic soil load for a 60-second contact time at room temperature (20°C):

Human Coronavirus (ATCC VR-740, Strain 229E)	499297-16
Herpes simplex virus type 1 ATCC VR-733, Strain F(1)	499297-17
Herpes simplex virus type 2 (ATCC VR-734, Strain G)	499297-18
2009-H1N1 Influenza A virus Novel H1N1 Strain	
A/Mexico/4108/2009 CDC #2009712192	499297-19
Respiratory syncytial virus (ATCC VR-26, Strain Long)	499297-20

Recoverable virus titers of at least  $10^4$  were achieved. Complete inactivation (no growth) was observed in all dilutions tested in studies where no cytotoxicity was observed. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

4. The submitted efficacy data **support** the ready-to-use product as a disinfectant with virucidal activity against the following virus on hard non-porous surfaces with 5% organic soil load for a 5-minute contact time at room temperature (20°C):

Rotavirus (ATCC VR-2018, Strain WA)	499297-21
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Recoverable virus titers of at least  $10^4$  were achieved. Complete inactivation (no growth) was observed in all dilutions tested in studies where no cytotoxicity was observed. At least a 3-Log reduction in titer was demonstrated beyond the cytotoxic level.

- The submitted efficacy data **support** the ready-to-use product as a non-food contact surface sanitizer against the following bacteria on hard, non-porous, non-food contact surfaces for a 10-second contact time at room temperature (20°C):

<i>Enterobacter aerogenes</i>	ATCC 13048	499297-22
<i>Staphylococcus aureus</i>	ATCC 6538	499297-22

- The submitted efficacy data **support** the ready-to-use product as a residual self-sanitizing surface sanitizer against the following bacteria on hard, non-porous, non-food contact surfaces at room temperature (20°C):

<i>Enterobacter aerogenes</i>	ATCC 13048	499297-23
<i>Staphylococcus aureus</i>	ATCC 6538	499297-23

- The submitted efficacy data **support** the ready-to-use product as a disinfectant with fungicidal activity as a hard surface fungistat at room temperature (20-21°C):

<i>Aspergillus niger</i>	ATCC 6275	499297-24
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Treated carriers showed no growth of test organism through seven days incubation while control carriers showed acceptable growth of test organism. Sterility controls did not show growth.

- The submitted efficacy data **support** the ready-to-use product as a disinfectant with fungicidal activity as a soft surface fungistat at room temperature (20-21°C):

<i>Aspergillus niger</i>	ATCC 6275	499297-25
<i>Penicillium variable</i>	ATCC 32333	499297-25

Treated carriers showed no growth of test organism through 7 day intervals over 28 days incubation while control carriers showed acceptable growth of test organism. Sterility controls did not show growth.

## VI RECOMMENDATIONS

- The label claims that the product is a ready-to-use disinfectant against the following organisms on hard, non-porous surfaces, for a 1-minute contact time:

<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Salmonella enterica</i>	ATCC 10708
<i>Escherichia coli</i> O157:H7	ATCC 43888
Herpes simplex virus type 1, Strain F(1)	ATCC VR-733
Human Coronavirus, Strain 229E	ATCC VR-740
Herpes simplex virus type 2, Strain G	ATCC VR-734



2009-H1N1 Influenza A virus  
Novel H1N1 Strain A/Mexico/4108/2009 CDC #2009712192  
Respiratory syncytial virus, Strain Long ATCC VR-26

These claims are acceptable as they are supported by the submitted efficacy data.

2. The label claims that the product is a ready-to-use disinfectant against the following organisms on hard, non-porous surfaces, for a 5-minute contact time:

Rotavirus, Strain WA	ATCC VR-2018
<i>Trichophyton mentagrophytes</i>	ATCC 9533
<i>Aspergillus niger</i>	ATCC 6275

These claims are acceptable as they are supported by the submitted efficacy data.

3. The label claims that the product is a non-food contact surface sanitizer against the following bacteria on hard, non-porous, non-food contact surfaces for a 10-second contact time:

<i>Enterobacter aerogenes</i>	ATCC 13048
<i>Staphylococcus aureus</i>	ATCC 6538

These claims are acceptable as they are supported by the submitted data.

4. The label claims that the product is a residual self-sanitizing surface sanitizer against the following bacteria for a 5-minute contact time on hard, non-porous, non-food contact surfaces:

<i>Enterobacter aerogenes</i>	ATCC 13048
<i>Staphylococcus aureus</i>	ATCC 6538

These claims are acceptable as they are supported by the submitted data.

5. The label claims that the product is a hard surface mildewstat with fungicidal activity against mold and mildew (*Aspergillus niger*, ATCC 6275) on hard, non-porous surfaces for a 7-day duration. This claim is acceptable as it is supported by the submitted data.
6. The label claims that the product is a fabric mildewstat with fungicidal activity against mold and mildew on soft surfaces (*Aspergillus niger* ATCC 6275 and *Penicillium variable* (ATCC 32333) for a 28-day duration. This claim is acceptable as it is supported by the submitted data.

## VI LABEL COMMENTS (version 101016):

- Page 1; Under "Condor 2," [Sanitizer], change to [non-food contact surface sanitizer]
- Page 2; {Sanitizing Directions} under DIRECTIONS FOR USE, include, "non-food contact surface."
- Page 3; under {Disinfecting Directions}, Where it says, "Wipe with a [damp] cloth [or sponge]..." change to read, *After the contact time, wipe with a ...*
- Page 3 (and anywhere else it may appear on the label); remove all references to "black mold" as the organism referenced does not support a black mold label claim.

- Page 3 and Page 8; Change [Fabric Mildewstat] to include "Spot Treatment" and revise {Fabric Mildewstat Claims} where necessary to limit use to spot treatments.
- Page 7; Near the top of the continuing list of {24 Hour Residual Sanitizing Claims}, remove "[disinfection]" from the claim, "Provides 24 hour [antimicrobial] [disinfection] against bacteria.
- Page 7 and 8; continued list of {24 Hour Residual Sanitizing Claims}, remove "germ free" and "free from germs."
- Page 8; When using quantitative measurements derived from qualitative data (i.e., Use Dilution and derivatives, Germicidal Spray Products Test, etc.), the maximum allowed claim is limited to 99.9% regardless of carrier counts reported. Change all instances of 99.9[9]% to 99.9% (multiple occurrences throughout the label).
  - Page 8; "Kills 99.9% of bacteria ... for 24 hours," include, "on treated surfaces."
  - Page 6; Remove "Prevents [bacterial growth]"
- Page 9; Revise {Emerging Pathogen Claims} as specified by current Agency guidance. Terms of Registration should be revised to reflect the language in Attachment 1 of the Emerging Viral Pathogen Guidance document.

[https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf)